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APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A  
FILING DATE.

APPLICATION NUMBER: 60/458,643

FILING DATE: March 28, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/09610

By Authority of the  
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Certifying Officer



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03-31-03 60458643 032803 2/2003

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# PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(c).

DOCKET NUMBER: B01075.70040  
Express Mail Label No. EV 208 517 808 US  
Date of Deposit: March 28, 2003

## INVENTOR(S)/APPLICANT(S)

LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)
Stevens-Wright	Debbie		North Andover, MA

☐ Additional inventors are being named on the separately numbered sheets attached hereto.

TITLE OF THE INVENTION (280 characters max)

METHOD AND APPARATUS FOR SELECTING TEMPERATURE/POWER SET POINTS IN ELECTROPHYSIOLOGY PROCEDURES

## CORRESPONDENCE ADDRESS

CUSTOMER NUMBER:



23628

## ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification - Number of Pages = 11

☐ Drawing(s) - Number of Sheets

☐ Application Data Sheet, See 37 CFR 1.76

☒ Return receipt postcard

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No

☐ Yes, the name of the U.S., Government Agency and the Government Contract Number are:

☐ Other:

## METHOD OF PAYMENT (check all that apply)

☒ A check is enclosed to cover the Provisional Filing Fees.

☐ The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

☐ Small Entity Status is claimed.

PROVISIONAL FILING FEE AMOUNT

\$ 160.00

Respectfully submitted,

March 28, 2003

Date

James H. Morris, Reg. No. 34,681  
Telephone No.: 617-720-3500

TITLE: Algorithm for ~~selecting a target temperature~~  
~~for temperature sensing and ablation~~

From Page No. 1

or target power for power control ablation

Dependent

Depending upon the surface extension of electrode toward the boundary of the ablation domain, the power requirements and the temperature sensing arrangement will vary from one electrode design. In addition, the flow conditions and proximity of the electrode to the tissue surface will affect these requirements. Traditionally, a single set point has been applied across varying flow conditions, geometries and tissue electrode gaps. The proposed computer algorithm includes an algorithm in which the set point (power or temperature) would depend upon:

Impedance  
 Tissue Gap  
 Flow

The impedance at the start of ablation is dependent upon the surface geometry of the electrode. The impedance increases the outer surface of the electrode extends towards the boundary of the ablation domain. Larger electrodes, requiring more power and have lower impedances.

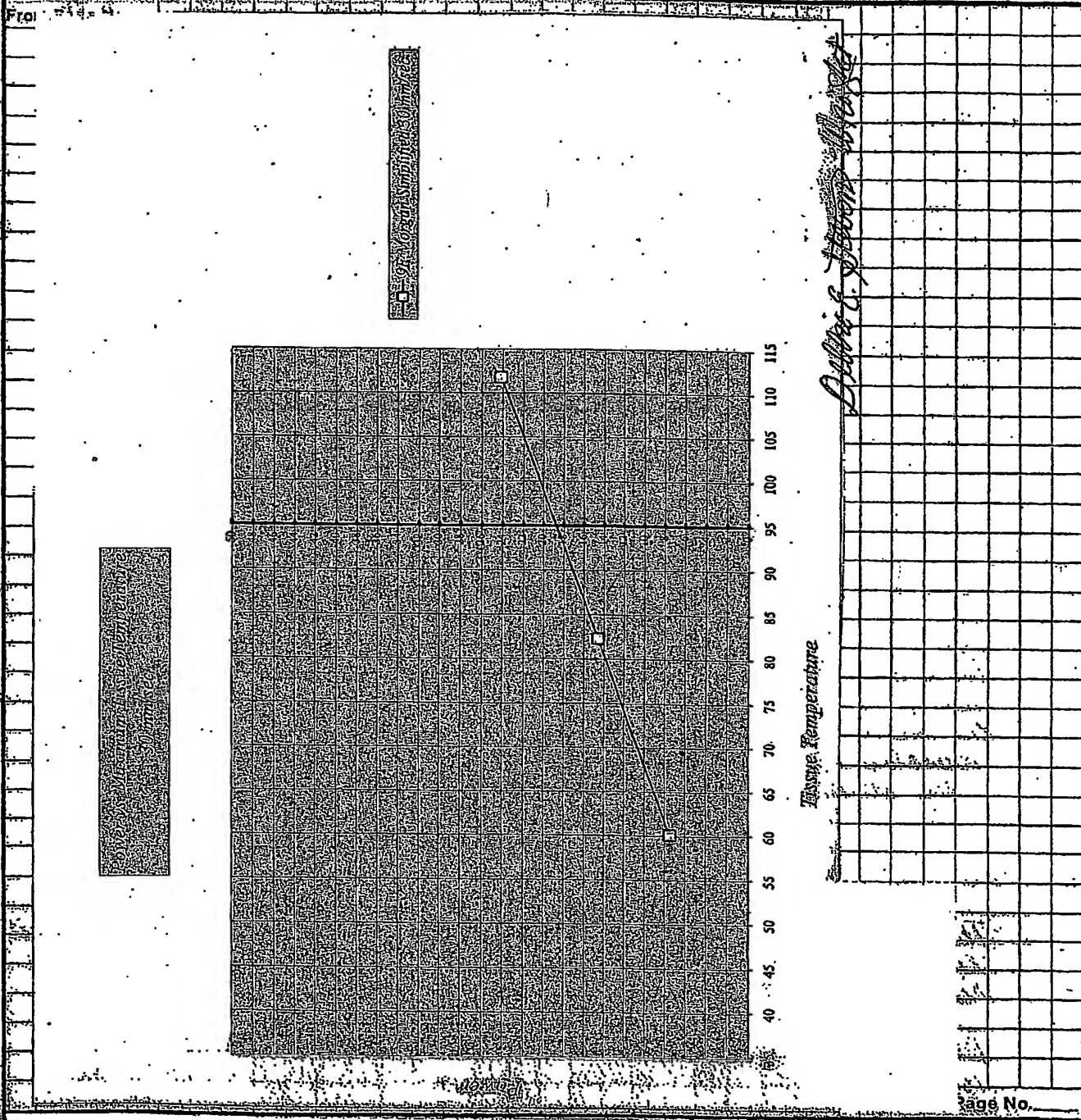
\*Larger tissue gaps, predominantly are beneficial at higher flows and smaller gaps beneficial at lower flows.

The difference between tissue temperature and electrode temperature increases with increasing flow. Therefore a given design will require a lower set point at higher flows.

Below is an example of how the FEA analysis can be used to predict the temperature set point for known impedance, electrode geometry, tissue gap, and flow.

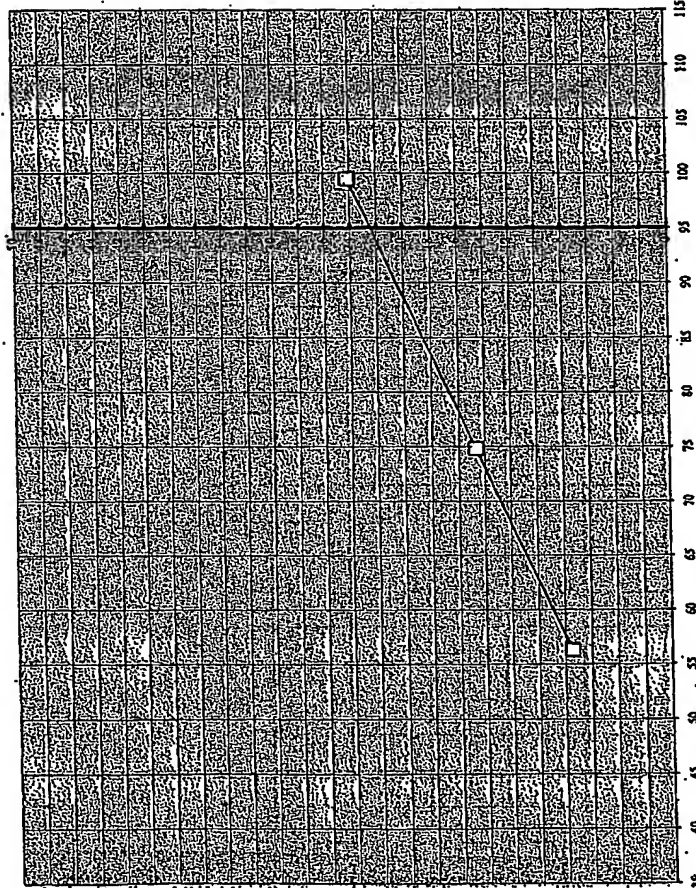
To Page No. 2

TITLE *Algebra - Temperature / Power Select*



TITLE

From Pa

TITLE *Algorithms of Temperature / Power Selection*From Page No. *1*Power vs. Maximum Tissue Temperature  
50 mm/sec

Tissue Temperature

*David E. Hirsch - Hirsch*

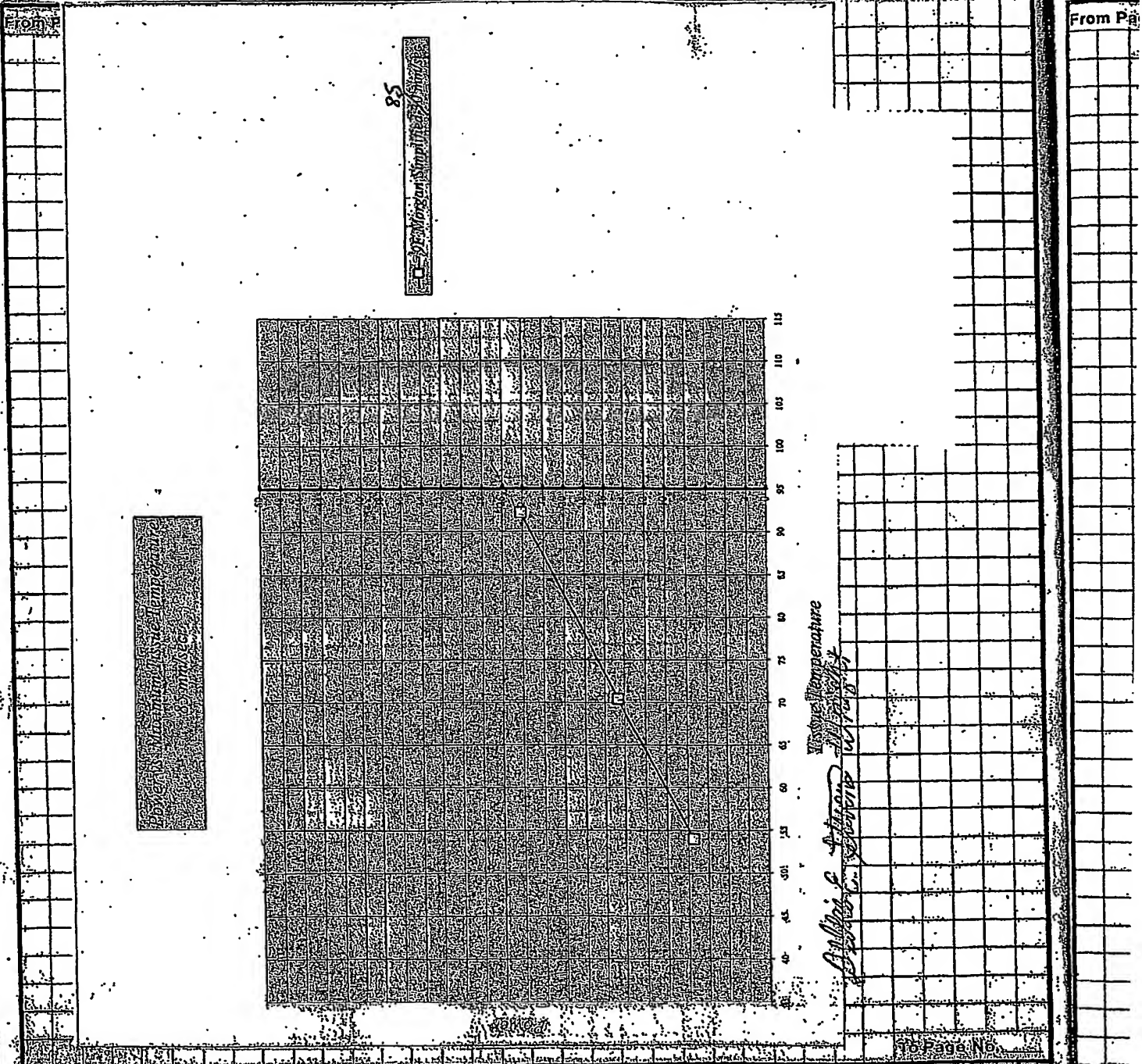
Page No.



18

TITLE *Algorithm - Temperature Power Select*

TITLE

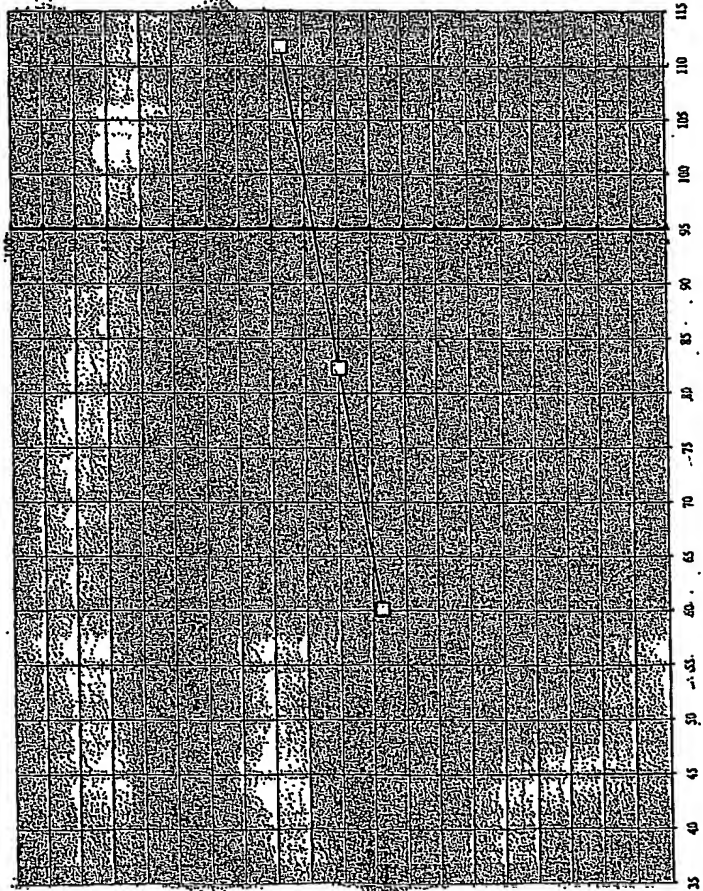


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TITLE *Location - Temperature / Power Dept*

From Page No. *12*

Maximum Tissue Temperature - Maximum Tissue Temperature  
50 mm/sec



Tissue Temperature

Maximum Tissue Temperature

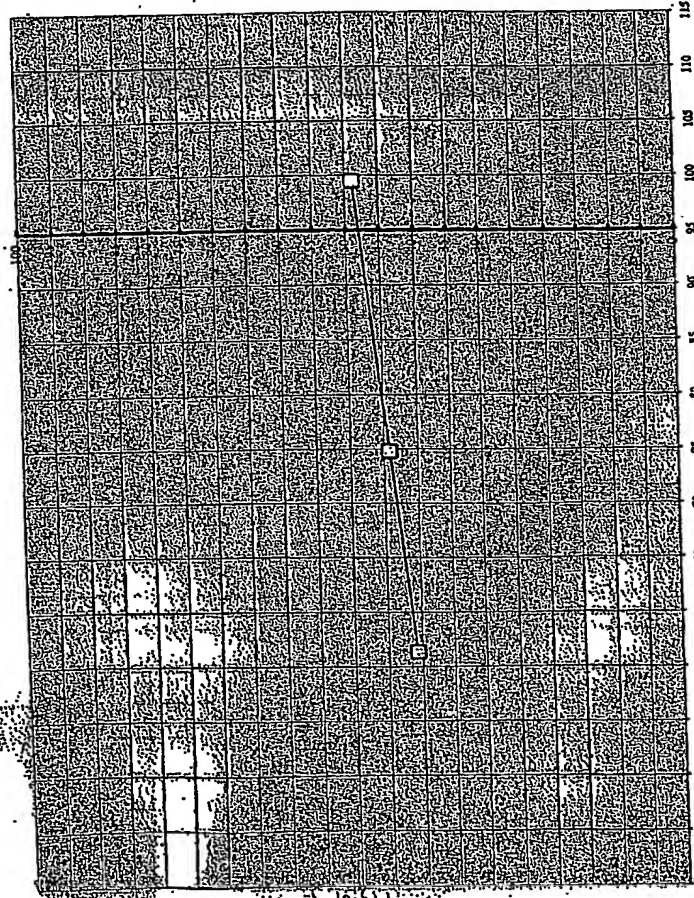
No. *2*

From Page

From Page

Maximum Ambient Temperature  
Maximum Ambient Temperature  
Maximum Ambient Temperature

Maximum Ambient Temperature



*Algorithm - Temperature / Power Select*

Temperature

Maximum Ambient Temperature

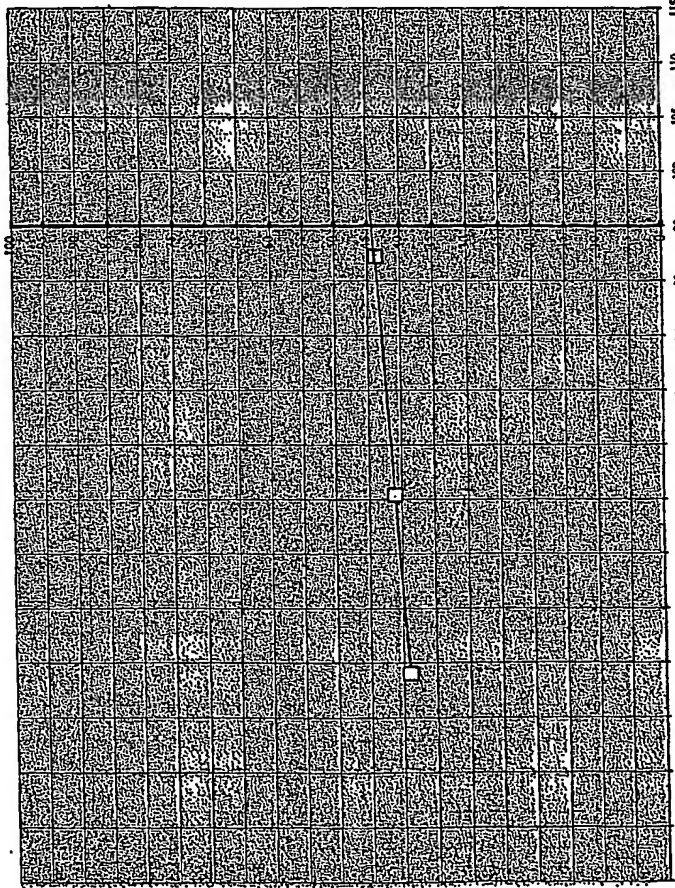
To Page No.



TITLE *Temperature of Power Plant*

From Page No.

Maximum Dielectric Temperature of Insulating Material



Tissue Temperature

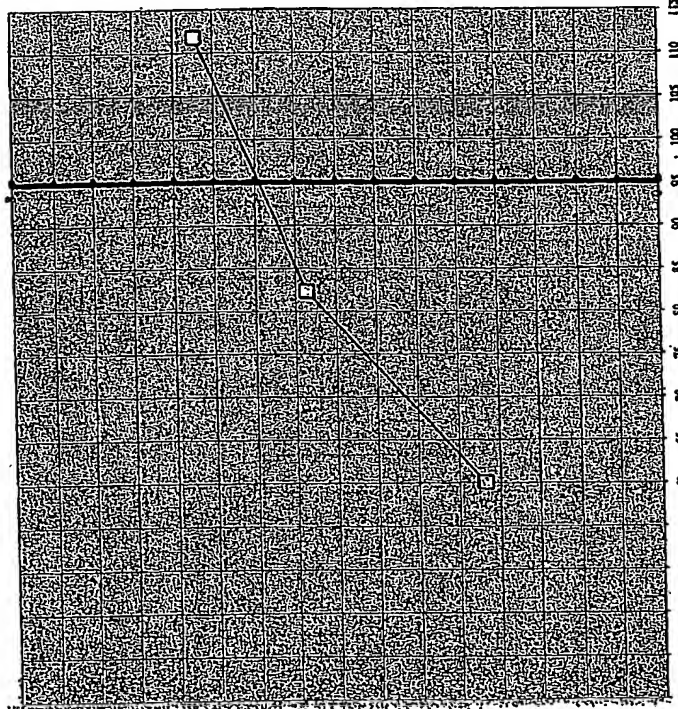
*Debris C. Tissue Masses*

Maximum Dielectric Temperature

Page No.

From Page 1

From

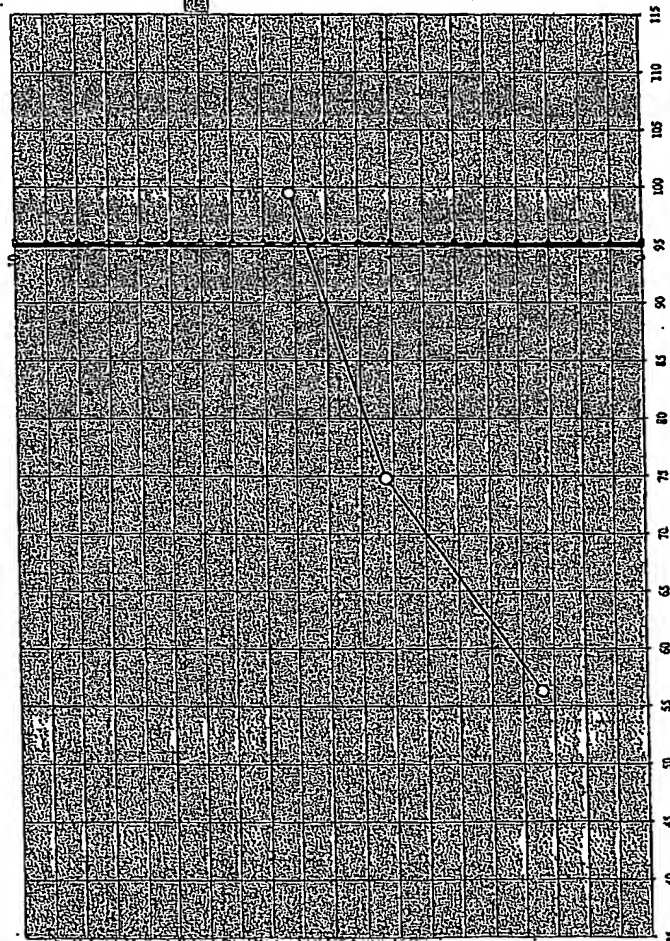


*David C. Edwards - March*

Expos Temperature

To Page No

From Page No.



***Tissue Temperature***

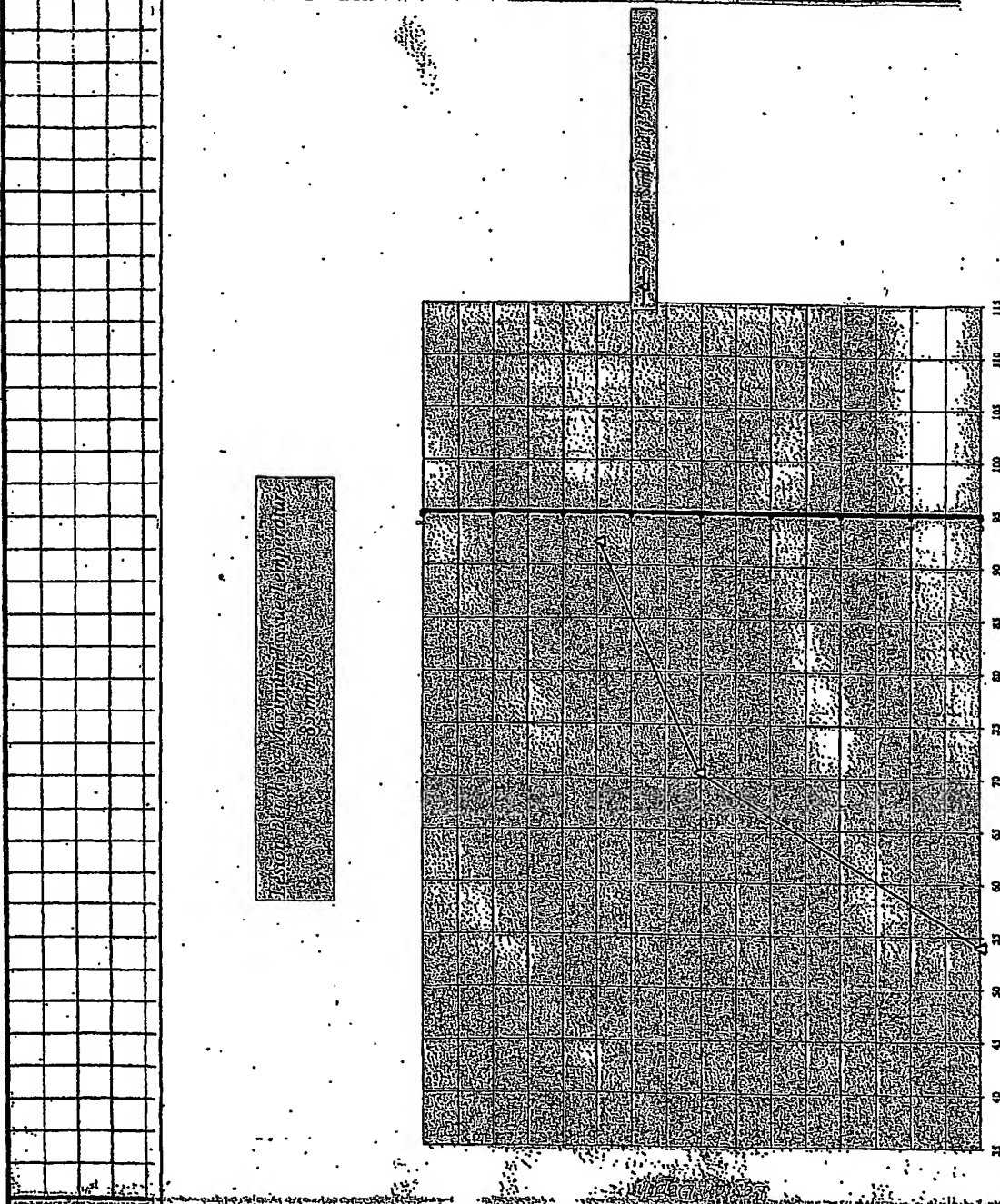
Julius E. S. Wagner

o Page No.

**To Page No.:** \_\_\_\_\_

core  
 TITLE *Debris E. Algorithm - Temperature / Power*

From Page No. \_\_\_\_\_



*Debris E. Algorithm - Temperature / Power*

Tissue Temperature

Page No. \_\_\_\_\_

TITLE

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W1140



TITLE Algorithm - Temperature / Power Selection

425

From Page No. \_\_\_\_\_

Electrode - Ablation Prescription (Preliminary)				
Flow	Impedance	Tissue Gap	Temperature Set Point	Power Set Point
mm/sec	ohms	in.	°C	W
30	83	.009 Embedded	54.0	Expected Lesion Generation
55	83	.009 Embedded	48.0	mm
85	83	.009 Embedded	44.5	4.93
				5.30
				5.65

*Dalai E. Durrant-Wright*

The preceding curves were generated from an FEA analysis where the applied potential was ranged at three flow rates (30mm/sec, 55mm/sec, 85 mm/sec). The allowable maximum allowable tissue temperature was chosen to be below 95°C. The set points were taken from plots of (Power vs Maximum tissue temperature) and (Maximum electrode temperature vs Maximum tissue temperature).

To Page No. \_\_\_\_\_

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